Regulatory Status of Caffeine

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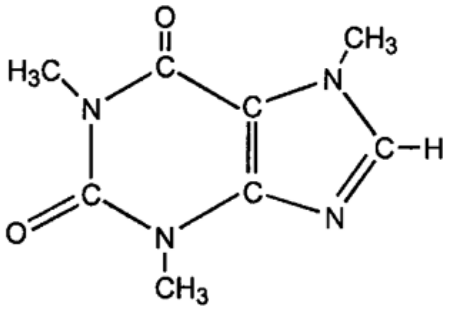
Outline

- Explain GRAS as it relates to food ingredients
- Review caffeine's regulatory status and history
- Describe FDA's current concerns re: safety
- Summarize FDA's work leading up to the recent IOM workshop on caffeine
- Discuss potential next steps

Caffeine

- Naturally present in coffee, tea, chocolate, and the cola nut extract used in cola-type beverages
- 1, 3, 7-trimethylxanthine
- Long history of safe use



Caffeine

Foods or dietary supplements?

Energy drinks marketed as "foods"

- Subject to FD&C Act
- Ingredients: approved food additives or GRAS for their intended uses

Energy drinks marketed as "dietary supplements"

- Subject to DSHEA
- Must be labeled as dietary supplements

Definition of "food additive"

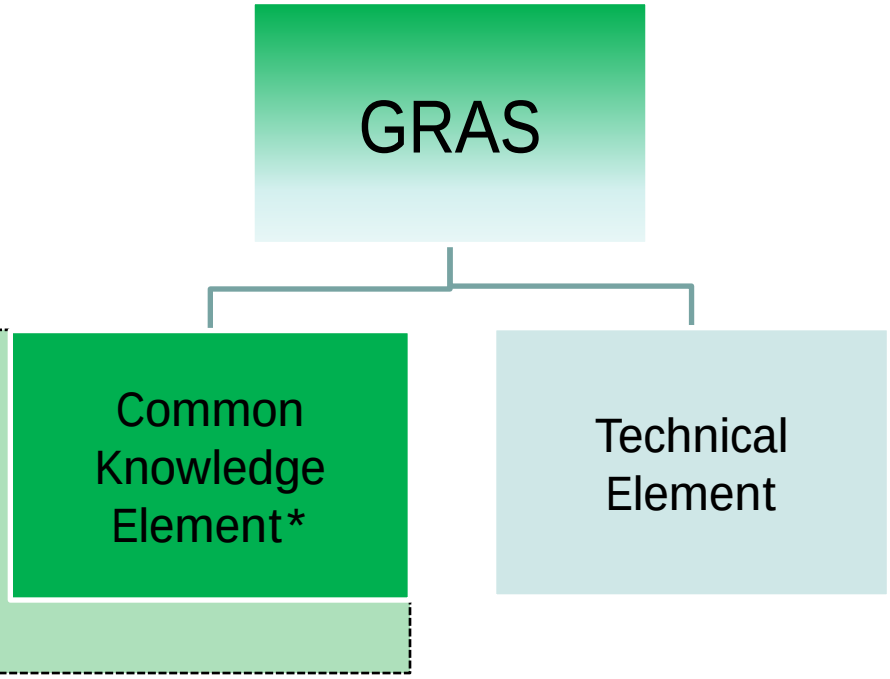
"…any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food…if such substance is not generally recognized, among experts qualified by scientific training…to be safe under the conditions of its intended use…"

(FD&C Act Section 201(s))

A substance added to food is a food additive unless.....

It is GRAS, i.e., generally recognized by qualified experts to be safe under the conditions of its intended use.

*Supportive information must be generally available and generally accepted by experts.



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The GRAS provision

- GRAS is:
  - Embedded in the FD&C Act (§ 201(s) and 409)
    - Not a pre-market approval; however,
    - Preserves FDA's pre- and post-market authority
  - Practical approach to allocating resources using scientific judgment
- GRAS is not:
  - an inherent quality of a substance
  - a lesser safety standard

Regulatory history

- Caffeine added to food is subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- According to 21 CFR 182.1180, caffeine up to a level of 0.02 percent (200 ppm) is generally recognized as safe (GRAS) for use in cola-type beverages (consistent with cGMPs).
  - The regulation does not automatically preclude other uses of caffeine from being considered GRAS.
  - And, it does not automatically give GRAS status to other uses and/or higher tolerances.
- The regulation was based on industry practice more than forty years ago.

More regulatory history

1978

- SCOGS; no hazard from use in soft drinks
- Questioned use as a CNS stimulant

1980-90

- FDA considered various regulatory options for caffeine
- FDA addressed scientific issues as new data and information became available

2000+

- 1959 regulation remained in effect
- Proliferation of new products

Caffeine labeling

- FDA regulations require beverage companies to list caffeine in the ingredients list on product labels.
- There is no FDA requirement to list the precise amount of caffeine present in a product.
- Voluntary labeling
  - Quantitative: Soda manufactures voluntarily label the amount of caffeine in accordance with American Beverage Association guidelines. More recently, energy drink manufacturers have begun to use the same guidelines
  - Cautionary statements: Some products contain advisories against use by children, pregnant women or individuals sensitive to caffeine.

Why is caffeine of such current concern to FDA?

- Products with added caffeine (both liquids and solids) are proliferating in the food supply.
- The patterns of use of caffeine-containing products are changing and not well understood.
- Caffeinated products are readily available and attractive to children and adolescents.
- Estimates of exposure to caffeine from all sources are approaching health reference values.

FDA caffeine activities

- Evaluating exposure
  - FDA's assessments: internal and external
  - ILSI's assessment, IOM's report for the military, and EFSA's report on intake in Europe
  - Exploring new sources of data to better understand what is entering the market place and patterns of intake for caffeinated products (e.g., food labels)
- Collecting toxicology data/safety information
  - Oak Ridge Contract Report (2011)
  - Adverse Event Reports in FDA's CAERS database
  - Other reports, e.g., caffeine-related calls to the National Poison Control Center and hospital emergency room visits reported by the Substance Abuse and Mental Health Services Administration

Food industry outreach

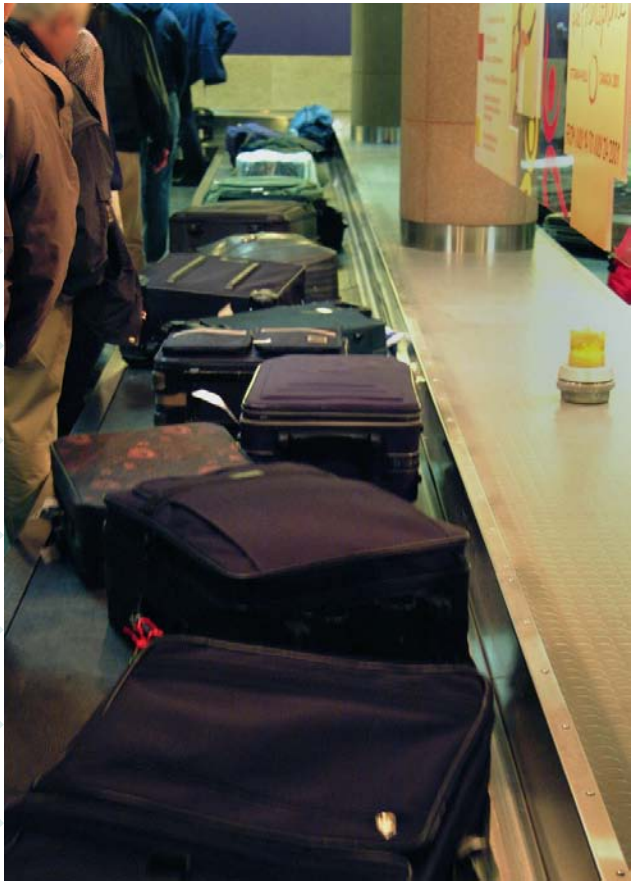
- FDA has talked with some companies to hear about their rationale for adding caffeine to different products and to share our concerns.
- Reached out to associations such as the American Beverage Association and the Grocery Manufacturers Association.
- Asked manufacturers of caffeinated products for information that demonstrates that they have evaluated the safety of ingredients as used in their products.

FDA sponsored IOM meeting

- FDA contracted with the Institute of Medicine (IOM) on April 23, 2013 to hold a public scientific meeting examining the safety of caffeine in food and dietary supplements.
- FDA provided reference material to IOM
  - "White paper" with a series of questions
  - Contract reports on estimates of caffeine exposure
  - Compilation of caffeine-related published safety data
  - Data on adverse events reports received by FDA)
- Workshop was held August 5-6, 2013 in DC

Not a typical food ingredient

- Human variability
- Public perception
- Age
- Culture
- Benefits
- Data interpretation
- Marketing
- Intended effect
- Health status



Closing thoughts

- FDA seeks transparency and open dialogue in resolving caffeine issues.
- FDA must identify the best available science.
- FDA will need to consider varied regulatory options to address caffeine.
- FDA will do what it takes to protect public health.

Risk Assessment

Analysis

Management

Communication

Thank you

For more information about food ingredients visit FDA's website.

www.fda.gov

Follow the links through foods to Food Ingredients & Packaging.